Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University

SESSION: Patient Study Calendar Functional Deep Dive

Session Information	**Date: May 31, 2007** **Time: 11:15 a.m. – 12:30 p.m. PDT** **Presenter/Lead: Sean Whittaker** **Facilitator: Niket Parikh** **Scribe: Karen Ryan**
Executive Summary	Application overview, features and functions implemented, roles and responsibilities. Through the Clinical Trials Management System Interoperability (CTMSi) project, Patient Study Calendar (PSC) has proven that it can receive patient registration information from Cancer Central Clinical Participant Registry (C3PR), and adverse events (AE) notifications from cancer Adverse Event Reporting System (caAERS). Phase 2 of PSC begins June 1. Participation is encouraged from the community. A demonstration version of the most current PSC release is available on the GForge site for download and local installation: http://gforge.nci.nih.gov/plugins/scmcvs/cvsweb.php/studycalendar/Final/?cvsroot=studycalendar. The PSC Phase 2 kickoff meeting is scheduled for June 8, 10–4 p.m., via teleconference. An invitation will be sent out via e-mail. The PSC team is encouraging community involvement and feedback. PSC is also seeking additional adopters.
Discussion	A demonstration of the latest version of PSC was provided, highlighting current features and functionality. This triggered an interactive discussion among from attendees.
Requirements	

Req. #	Name	Description
1	Tracking CRF Activity	An inquiry was made about adding Case Report Forms (CRF) activity and tracking what needs to be collected for the study. Developers are already considering the possibility of adding this as an activity within the PSC.
2	Import of protocol definitions	Consider adding the ability to upload protocol definition after the protocol receives Institutional Review Board (IRB) approval. Potential new feature to allow import of study metadata.
3	Varying views of the calendar	A printable daily calendar would be helpful, from the CRA perspective, to be able to view the day's activities. Currently, the reporting options are patient-centric. Perhaps this could be extended to allow study-centric, and also CRA centric (across all patients and studies they are responsible for) views, as well as a multi-site study view (depending on privileges) of activities might be provided that cross multi-sites.
4	CRA assignments	Consider assignment of patients, studies, and sites to CRAs. For example: Mayo assigns a CRA to a study, others assign each CRA to a number of patients. Consider how this might affect the best way to provide reporting, and

			filtering of studies based on workload.
	5	CRA to-do list, tracking CRF form submissions	Some CRAs work from a "to-do" list rather than a calendar and are chronologically focused on what is overdue today, tomorrow, etc. Need to know "where did the patient stop," how do I get them back on track? Tracking the actual CRF forms. Consider CRF submission automatically so that the system removes or marks activities as completed as they occur. Turnover or lack of funding sometimes makes things fall behind. Form submissions are often overdue, i.e., it is not necessarily the treatments themselves that are overdue.
	6	iCal interaction	Consider an electronic interaction or tie-back to other technologies (e-mail, Outlook or other calendars, patient scheduling system). Provide for electronic notifications to CRA or patients. Out of scope for current project, but the hooks may be implementable, using current scheduling standards. Issues with "time" based assignments: currently PSC assigns activities to be tagged with a "day" and moving towards hourly assignment of activities with overlap with Doctor's Calendar/Scheduling.
	7	Billing information	Could the PSC provide tracking of financial billing information associated with activities (laboratory tests), and perhaps flag which activities have billing concerns? This is currently out of scope , however, this could be placed into a "categorization" of activities, e.g., billing activities, laboratory-related activities
	8	View of patient track	Consider a graphical representation of the patient "path" overlaid over the protocol arms.

Issues

Issue ID	Description
1	Some concern was expressed, including treatment dosage on the patient calendar. Concern from the risk assessment perspective. The developers have accommodated this by allowing for flexibility in how the information gets displayed on the patient calendar.
2	Need to be able to handle protocol amendments - developers will be analyzing this area and the impact of these to the patient level. Allow changes to the study template based on these amendments. Engage proper SMEs and consider protocol authoring tools.
3	Importing and exporting of templates, to facilitate the ability to save and reuse the study templates. Protocol authoring tool for template structure and deriving data (awareness/engagement).

Action Items

Assigned To	Description	Due Date

Attendance

#	First Name	Last Name	Affiliation

1.	Ram	Chilukuri	SemanticBits
2.	Cal	Collins	Akaza
3.	Deborah	Collyar	PAIR
4.	Leslie	Derr	NCI CBIIT
5.	Doug	Fridsma	Univ of Pittsburgh
6.	Amy	Funkhouser	ECOG
7.	Allison	Geer	Velos, Inc.
8.	Robin	Harris	Arizona
9.	Smita	Hastak	ScenPro
10.	Julie	Holtzople	Booz Allen Hamilton
11.	Andrea	Hwang	UCI
12.	Christie	Kaefer	NCI CBIIT
13.	Warren	Kibbe	Northwestern
14.	Jieping	Li	Georgetown
15.	Brenda	Maeske	SAIC
16.	Missy	McAdoo	UAMS
17.	Patrick	McConnell	Duke
18.	Bob	Morrell	WFU
19.	Ed	Mulaire	SemanticBits
20.	Sorena	Nadaf	Vanderbilt
21.	Susan	Pannoni	City of Hope
22.	Niket	Parikh	Booz Allen Hamilton
23.	Gopi	Potnuru	PercipEnz
24.	Karen	Ryan	Booz Allen Hamilton
25.	Linda	Schmandt	Univ of Pittsburgh
26.	Ann	Setser	NCI / CTEP
27.	Angela	Smith	SWOG
28.	Rhett	Sutphin	Northwestern

	29.	Umit	Topaloglu	UAMS
	30.	Troy	Walls	UAMS
	31.	Sean	Whitaker	Northwestern